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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,599	11/29/2001	Masayasu Ogushi	216644US0	2699

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EXAMINER	
AUGHENBAUGH, WALTER	

ART UNIT	PAPER NUMBER
1772	8

DATE MAILED: 07/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

mk-8

Office Action Summary	Application N .	Applicant(s)	
	09/995,599	OGUSHI ET AL.	
	Examiner	Art Unit	
	Walter B Aughenbaugh	1772	

-- Th MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 1, the claim (or specification) does not specify what is meant by the acronyms "MD" and "TD". The claims must include what is meant by these acronyms; please insert "machine direction" and "transverse direction" into the claims provided this is indeed what is intended.

In regard to claim 2, the structure intended to be recited by the limitation "on an outer peripheral surface" cannot be ascertained. What is "on an outer peripheral surface"? "On an outer peripheral surface" of what?

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3, 4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al.

Ahmed et al. teach medical devices (col. 1, lines 40-48) and more specifically medical tubing (col. 16, lines 15-19) (and therefore a medical tube) obtained by subjecting a resin composition comprising a styrenic elastomer and a polyolefin to blow molding or extrusion molding (col. 1, lines 21-26, col. 13, lines 53-64, col. 14, lines 23-54, col. 15, lines 25-36 and col. 16, lines 31-43). Ahmed et al. teach that various blends of the composition have storage modulus values that fall within the claimed storage modulus value range of $5.0*10^7$ dynes/cm^2 to $8.0*10^8$ dynes/cm^2 at 24°C (col. 15, lines 37-41 and col. 18, line 35-col. 19, line 25, Table 1 [col.18-col.19], Tables 2-4 and Fig. 1).

The term "endotracheal" in the phrase "endotracheal tube" is an intended use recitation that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987). Note that no structure is claimed which limits the claimed tube to solely an endotracheal tube.

The recitations "obtained by subjecting" and "to extrusion-molding" are method limitations that have been given little patentable weight since the method of forming the tube is not germane to the issue of patentability of the tube itself.

Ahmed et al. fail to teach that the tube has a ratio of the storage modulus (MD) in the extrusion direction to a storage modulus (TD) in the circumferential direction (MD/TD) of not more than 1.3 at 25°C. However, since the storage modulus values of the composition of Ahmed et al. at 24°C fall within the range of storage modulus values at 25°C recited in claim 1, in the absence of convincing objective evidence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected compositions from within the disclosure of Ahmed et al. that have the claimed ratio of the storage modulus (MD) in the extrusion direction to a storage modulus (TD) in the circumferential direction (MD/TD) , and to have subjected the composition of Ahmed et al. to an extrusion process such that the claimed storage modulus ratio is obtained.

In regard to claim 3, Ahmed et al. teach that the styrenic elastomer is a block copolymer of a styrenic polymer block and a hydrogenated conjugated diene polymer block (col. 23-54). In regard to claim 4, Ahmed et al. teach that the hydrogenated conjugated diene polymer block is a hydrogenated polyisoprene block (col. 14, lines 43-44), a hydrogenated isoprene/butadiene copolymer block (col. 14, lines 43-44 and 54-64) or a hydrogenated polybutadiene block (col. 14, lines 38-42).

In regard to claim 8, Ahmed et al. teach that the content of the styrenic polymer block in the block copolymer is 8-65% by weight, a range that completely envelopes the claimed range of 10 to 40%, and Ahmed et al. teach that the content of the styrenic polymer block in the block

copolymer is preferably 10-35% by weight, a range that falls completely within the claimed range of 10-40% (col. 14, line 65-col. 15, line 1).

5. Claims 2 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. in view of Sterling.

Ahmed et al. teach the medical tube as discussed above. Ahmed et al. teach that blow molding is a suitable method of forming the composition into an article (col. 15, line 64-col. 16, line 10). In regard to claim 2, Ahmed et al. fail to teach that the tube is provided with a cuff formed from the resin composition comprising a styrenic elastomer and a polyolefin taught by Ahmed et al. on an outer peripheral surface, that the cuff has a storage modulus of not more than $5.0*10^8$ dynes/cm^2 at 25°C and that the resin composition of the cuff has a melt tension of not less than 1g at 230°C. Sterling, however, discloses an endotracheal tube (item 33) having a shaft (item 34) and a cuff (item 41) that are both formed from a blend comprising styrene-ethylene-butylene-styrene block copolymer and polypropylene (col. 7, lines 1-4 and 27-31, col. 15, lines 17-36 and 52-60 and Fig. 6 and 15). Sterling discloses that the blend comprising styrene-ethylene-butylene-styrene block copolymer and polypropylene can undergo conventional blow molding techniques (col.14, line 58-col. 15, line 7). Therefore, one of ordinary skill in the art would have recognized to have blow molded the resin composition comprising a styrenic elastomer and a polyolefin taught by Ahmed et al. which has a storage modulus of not more than $5.0*10^8$ dynes/cm^2 at 24°C into a cuff in order to form the medical tube of Ahmed et al. into an endotracheal tube since it is known to form an endotracheal tube having a shaft and a blow molded cuff that are both formed from a blend comprising a styrenic block copolymer and a polyolefin as taught by Sterling.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have blow molded the resin composition comprising a styrenic elastomer and a polyolefin taught by Ahmed et al. which has a storage modulus of not more than $5.0*10^8$ dynes/cm^2 at 24°C into a cuff in order to form the medical tube of Ahmed et al. into an endotracheal tube since it is known to form an endotracheal tube having a shaft and a blow molded cuff that are both formed from a blend comprising a styrenic block copolymer and a polyolefin as taught by Sterling.

The recitations "obtained by subjecting" and "to blow-molding" are method limitations that have been given little patentable weight since the method of forming the cuff is not germane to the issue of patentability of the cuff itself.

In regard to the claimed melt tension of the resin composition of the cuff of not less than 1g at 230°C, the selection of polymeric compositions having suitable melt tension for the particular desired end use would have been obvious to one of ordinary skill in the art at the time the invention was made, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In regard to claims 10 and 11, Ahmed et al. teach that additives such as fillers can be included in the resin composition (col. 15, lines 50-58). Ahmed et al. fail to teach that the filler is present in an amount of 5 to 20% by weight (as claimed in claim 10) and that the filler is one of the chemical species claimed in claim 11. Sterling, however, discloses that the block copolymer/polypropylene blend contains up to 25% polystyrene as an additive (col. 4, lines 54-55) that improves the rheological properties of the blend (col. 11, lines 5-6). Sterling discloses

that the polymeric components (i.e. the elastomeric block copolymer, the polypropylene and the polystyrene additive) are introduced as a mixture in pellet form (col. 11, lines 26-32), which Examiner interprets to be structurally equivalent to beads as claimed. Therefore, one of ordinary skill in the art would have recognized to have added crosslinked polystyrene beads in an amount of 5 to 20% by weight to the composition of Ahmed et al. in order to improve the rheological properties of the blend as taught by Sterling.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added crosslinked polystyrene beads in an amount of 5 to 20% by weight to the composition of Ahmed et al. in order to improve the rheological properties of the blend as taught by Sterling.

In regard to claim 12, Ahmed et al. teach the resin composition for medical devices comprising a styrenic elastomer and a polyolefin having a storage modulus of not more than $5.0*10^8$ dyne/cm^2 at 25°C as discussed above. Ahmed et al. teach that blow molding is a suitable method of forming the composition into an article (col. 15, line 64-col. 16, line 10). Ahmed et al. fail to teach that the resin composition is formed into a cuff and that the resin composition has a melt tension of not less than 1g at 230°C. Sterling, however, discloses a cuff (item 41) of an endotracheal tube (item 33) that are both formed from a blend comprising styrene-ethylene-butylene-styrene block copolymer and polypropylene (col. 7, lines 1-4 and 27-31, col. 15, lines 17-36 and 52-60 and Fig. 6 and 15). Sterling discloses that the blend comprising styrene-ethylene-butylene-styrene block copolymer and polypropylene can undergo conventional blow molding techniques (col.14, line 58-col. 15, line 7). Therefore, one of ordinary skill in the art would have recognized to have blow molded the resin composition comprising a styrenic

elastomer and a polyolefin taught by Ahmed et al. which has a storage modulus of not more than $5.0*10^8$ dynes/cm^2 at 24°C into a cuff in order to form a cuff of an endotracheal tube since it is known to form an endotracheal tube having a shaft and a blow molded cuff that are both formed from a blend comprising a styrenic block copolymer and a polyolefin as taught by Sterling.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have blow molded the resin composition comprising a styrenic elastomer and a polyolefin taught by Ahmed et al. which has a storage modulus of not more than $5.0*10^8$ dynes/cm^2 at 24°C into a cuff in order to form a cuff of an endotracheal tube since it is known to form an endotracheal tube having a shaft and a blow molded cuff that are both formed from a blend comprising a styrenic block copolymer and a polyolefin as taught by Sterling.

The recitations "obtained by subjecting" and "to blow-molding" are method limitations that have been given little patentable weight since the method of forming the cuff is not germane to the issue of patentability of the cuff itself.

In regard to the claimed melt tension of the resin composition of the cuff of not less than 1g at 230°C, the selection of polymeric compositions having suitable melt tension for the particular desired end use would have been obvious to one of ordinary skill in the art at the time the invention was made, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

6. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. in view of Ishii et al.

In regard to claim 5, Ahmed et al. teach the tube as discussed above. Furthermore, Ahmed et al. teach that the hydrogenated conjugated diene polymer block is a hydrogenated polyisoprene block (col. 14, lines 43-44) and that the polyisoprene block is hydrogenated such that at least 80% of the carbon-carbon double bonds of the polyisoprene are hydrogenated (col. 14, lines 54-64), a range that overlaps with the claimed range of "not less than 70%". Ahmed et al. fail to teach that the hydrogenated polyisoprene block has a 1,2-bond and 3,4-bond content of 10 to 75% by mol. Ishii et al., however, teach a composition for use in medical devices such as catheter tubes having a suitable flexibility and transparency for medical applications (paragraphs 1 and 2 of Detailed Description section of translation of JP 10-067894) Ishii et al. teach that the composition comprises a polypropylene-block copolymer blend comprising a block copolymer having a polyisoprene block that has a 1,2-bond and 3,4-bond content of 10 to 75% by mole (lines 1-3 of paragraph 6). Therefore, one of ordinary skill in the art would have recognized to have polymerized the polyisoprene block of Ahmed et al. such that the polyisoprene block has a 1,2-bond and 3,4-bond content of 10 to 75% by mole in order to form a tube having a suitable flexibility and transparency for medical applications as taught by Ishii et al. (paragraphs 1, 2 and 12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have polymerized the polyisoprene block of Ahmed et al. such that the polyisoprene block has a 1,2-bond and 3,4-bond content of 10 to 75% by mole in order to form a tube having a suitable flexibility and transparency for medical applications as taught by Ishii et al.

In regard to claim 6, Ahmed et al. teach the tube as discussed above. Furthermore, Ahmed et al. teach that the hydrogenated conjugated diene polymer block is a hydrogenated

isoprene/butadiene copolymer block (col. 14, lines 43-44) and that the isoprene/butadiene copolymer block is hydrogenated such that at least 80% of the carbon-carbon double bonds of the isoprene/butadiene copolymer are hydrogenated (col. 14, lines 54-64), a range that overlaps with the claimed range of "not less than 70%". Ahmed et al. fail to explicitly teach that the isoprene/butadiene copolymer is obtained by copolymerizing isoprene and butadiene in a weight ratio of 5/95 to 95/5 and that the isoprene/butadiene copolymer block has a 1,2-bond and 3,4-bond content of 20 to 85% by mole. However, the polypropylene-block copolymer blend taught by Ishii et al. comprises a block copolymer having an isoprene/butadiene block that is obtained by copolymerizing isoprene and butadiene in a weight ratio of 5/95 to 95/5 and that has a 1,2-bond and 3,4-bond content of 20 to 85% by mole (lines 6-8 of paragraph 6). Therefore, one of ordinary skill in the art would have recognized to have polymerized the isoprene/butadiene copolymer block of Ahmed et al. in a weight ratio of 5/95 to 95/5, and such that the isoprene/butadiene copolymer block has a 1,2-bond and 3,4-bond content of 20 to 85% by mole, in order to form a tube having a suitable flexibility and transparency for medical applications as taught by Ishii et al. (paragraphs 1, 2, 16 and 17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have polymerized the isoprene/butadiene copolymer block of Ahmed et al. in a weight ratio of 5/95 to 95/5, and such that the isoprene/butadiene copolymer block has a 1,2-bond and 3,4-bond content of 20 to 85% by mole, in order to form a tube having a suitable flexibility and transparency for medical applications as taught by Ishii et al.

In regard to claim 7, Ahmed et al. teach the tube as discussed above. Furthermore, Ahmed et al. teach that the hydrogenated conjugated diene polymer block is a hydrogenated

polybutadiene block (col. 14, lines 43-44) and that the polybutadiene block is hydrogenated such that at least 80% of the carbon-carbon double bonds of the polybutadiene are hydrogenated (col. 14, lines 54-64), a range that overlaps with the claimed range of "not less than 70%". Ahmed et al. further teach that the polybutadiene block has a 1,2-bond content of about 35 to about 55 mole % (col. 14, lines 38-41), a range that overlaps with the claimed 1,2-bond content of "not less than 45% by mol[e]". Ahmed et al. fail to teach that the hydrogenated polybutadiene block has a 3,4-bond content of not less than 45% by mole. However, the polypropylene-block copolymer blend taught by Ishii et al. comprises a block copolymer having an isoprene/butadiene block that has a 1,2-bond and 3,4-bond content of 20 to 85% by mole (lines 6-8 of paragraph 6), a range that overlaps with the claimed range of "not less than 45%. Therefore, one of ordinary skill in the art would have recognized to have polymerized the polybutadiene block of Ahmed et al. such that the polybutadiene block has a 3,4-bond content of not less than 45% by mole in order to form a tube having a suitable flexibility and transparency for medical applications as taught by Ishii et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have polymerized the polybutadiene block of Ahmed et al. such that the polybutadiene block has a 3,4-bond content of not less than 45% by mole in order to form a tube having a suitable flexibility and transparency for medical applications as taught by Ishii et al.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. in view of Ikematu et al.

Ahmed et al. teach the medical tube as discussed above. Ahmed et al. fail to teach that the resin compostion of the tube comprises at least one lubricant selected from the group consisting

of a fatty acid amide lubricant and a fatty acid monoglyceride lubricant in an amount of 0.05 to 0.5% by weight. Ikematu et al., however, disclose a styrenic block copolymer (col. 7, lines 38-46) used as a medical instrument material (col. 13, lines 21-28) that is formed into a tube (col. 13, lines 35-36). Ikematu et al. disclose that the composition comprises a lubricant such as fatty acid amide in an amount of 0.01 to 2 parts by weight per 100 parts of resin (col. 12, lines 3-24), an amount that overlaps with the claimed range of 0.05 to 0.5%. Therefore, one of ordinary skill in the art would have recognized to have added fatty acid amide to the polymeric composition of Ahmed et al. in order to lower the coefficient of friction of the tube of Ahmed et al. with respect to any opposing surface (i.e. lubricate the tube) since it is known to add lubricants such as fatty acid amide to tubes used in medical applications as taught by Ikematu et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added fatty acid amide to the polymeric composition of Ahmed et al. in order to lower the coefficient of friction of the tube of Ahmed et al. with respect to any opposing surface (i.e. lubricate the tube) since it is known to add lubricants such as fatty acid amide to tubes used in medical applications as taught by Ikematu et al.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,310,138 to Yonezawa et al., US 6,303,200 to Woo et al., US 6,221,448 to Baetzold et al., US 5,583,182 to Asahara et al., US 5,397,519 to Majumdar, US 4,616,064 to Zukosky et al., US 3,865,776 to Gergen.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 703-305-

4511. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 703-308-4251. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

wba
07/18/03 WBA